UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,	:	02 Civ. 8917 (KMW)(HBP)
Plaintiffs,	:	OPINION AND ORDER
-against-	:	
APOTEX CORPORATION and NOVEX PHARMA,	:	
Defendants.	:	

PITMAN, United States Magistrate Judge:

I. Introduction

This Order addresses the construction of three claim terms in this patent infringement suit. Each party has submitted proposed constructions for the disputed terms.

II. Facts

Plaintiffs are the owners of the two patents in suit, United States Patent No. 5,733,569 (the "'569 Patent") and United States Patent No. 5,759,565 (the "'565 Patent"). Both patents are entitled "Galenic Compositions Comprising Calcitonin and their Use" and claim compositions, devices, applicators and methods for the medical administration of calcitonin. Calcitonin

is a polypeptide hormone that occurs naturally in human beings that inhibits bone "resorption." Dorland's Illustrated Medical Dictionary 252 (27th ed. 1988) ("Dorland's"). Bone resorption is "a type of bone loss . . . due to osteoclastic activity." Dorland's at 1450. Calcitonin can be used medicinally to treat bone resorption-related diseases like Paget's disease, hypercalcemia and osteoporosis (Declaration of Alexander M. Klibanov, dated March 4, 2004 ("Klibanov Decl.") ¶ 18). Calcitonin can be obtained from a number of different animals including salmon, pigs and eels, and it can be synthesized or produced through genetic engineering (Klibanov Decl. ¶¶ 18-19).

Polypeptides, such as calcitonin, are broken down by the human digestive system, making oral administration impractical (Klibanov Decl. ¶ 22; '569 Patent, col. 1, lines 27-32; '565 Patent, col. 1, lines 27-32). Administration by injection is frequently undesirable because of the pain and the need for medical training to administer an injection; these difficulties sometimes result in reduced patient compliance with treatment regimens (Klibanov Decl. ¶ 23; '569 Patent, col. 1, lines 35-37; '565 Patent, col. 1, lines 35-37). The subject matter of the patents in suit seeks to eliminate these problems by disclosing an easy, painless and simple alternative means of administering calcitonin, to wit, nasal inhalation.

Claim 1 of the '569 Patent claims:

> 1. A liquid pharmaceutical composition comprising in a form suitable for administration as a liquid nasal spray:
>
> a a therapeutically effective amount of a calcitonin or a pharmaceutically acceptable acid addition salt thereof, wherein said calcitonin is selected from the group consisting of salmon calcitonin, human calcitonin, porcine calcitonin and 1.7-Asu-eel calcitonin;
>
> b an effective amount of benzalkonium chloride to enhance the bioavailability of said calcitonin when administered, to the nasal mucosa, and
>
> c a pharmaceutically acceptable, aqueous liquid nasal carrier.

Claim 1 of the '565 Patent claims:

> 1. A liquid pharmaceutical composition comprising 1) a pharmaceutically acceptable, aqueous liquid nasal carrier; 2) a therapeutically effective amount of a calcitonin or a pharmaceutically acceptable acid addition salt thereof, wherein said calcitonin is selected from the group consisting of salmon calcitonin, human calcitonin, porcine calcitonin and 1.7-Asu-eel calcitonin; and 3) about 0.002% to about 0.02% on a weight per volume basis of a benzalkonium chloride, said composition being in a form suitable for nasal administration.

Benzalkonium chloride was initially believed to be useful as a preserving agent. The patents in suit disclose that benzalkonium chloride also had a "surprising[]" effect of enhancing the bioavailability of calcitonin:

> Surprisingly it has also been found that use of benzalkonium chloride, even at the very low concentration required for use as a preserving agent, may confer beneficial advantages in relation to the nasal resorp-

> tion characteristics of calcitonin containing compositions and hence enhance calcitonin bio-availability levels consequential to nasal application.

('569 Patent, col. 2, lines 61-67; '565 Patent, col. 2, lines 61-67).

Plaintiffs are exploiting the patents in suit through their marketing of "MIACALCIN® Nasal Spray," a nasally administered salmon calcitonin formulation that plaintiffs contend is covered by the patents at issue (Plaintiffs' Opening Claim Construction Brief ("Pl. Memo."), Docket Item 54, at 4). This suit arose after defendants filed an abbreviated new drug application with the United States Food and Drug Administration to market a generic version of the MIACALCIN® Nasal Spray (Defendants Apotex Corp. and Novex Pharma's Memorandum of Law Regarding the Construction of the Parties' Disputed Terms Set Forth in the Asserted Claims of the Patents in Suit ("Def. Memo."), Docket Item 51, at 2).

III. Analysis

A. Standards for Claim Construction

Where the meaning of patent claim terms is in dispute, the court must construe the patent claims by determining their scope and meaning. See United States Philips Corp. v. Iwasaki Elec. Co, 03 Civ. 0172 (PKC), 2006 WL 20504 at *1 (S.D.N.Y. Jan.

3, 2006), citing Cyber Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998). Claim construction is a question of law to be decided by the Court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996).

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc), cert. denied, -- S.Ct. --, 2006 WL 386393, 74 U.S.L.W. 3464, 74 U.S.L.W. 3471 (U.S. Feb. 21, 2006) (Mo. 05-602) (internal quotation marks omitted). The words of a claim are generally given their "ordinary and customary" meaning, which is the meaning that the term would have to "a person of ordinary skill in the art in question at the time of the invention." Phillips v. AWH Corp., supra, 415 F.3d at 1312-13 (internal quotation marks omitted). "[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms." Phillips v. AWH Corp., supra, 415 F.3d at 1314.

The claims, however, do not stand alone. "Rather they are part of 'a fully integrated written instrument,' consisting principally of a specification that concludes with the claims." Phillips v. AWH Corp., supra, 415 F.3d at 1315, quoting Markman v. Westview Instruments, Inc., supra, 52 F.3d at 978. Thus, "[t]he specification 'is always highly relevant to the claim

construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Phillips v. AWH Corp., supra, 415 F.3d at 1315, quoting Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "Claims 'must be read in view of the specification, of which they are a part.'" Phillips v. AWH Corp., supra, 415 F.3d at 1315, quoting Markman v. Westview Instruments, Inc., supra, 52 F.3d 978-79. However, limitations from the specification may not be read into the claim. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 904 (Fed. Cir.), cert. denied, 543 U.S. 925 (2004). The Federal Circuit has noted there is a "fine line" between reading the claims in view of the specification and reading limitations from the specifications into the claims. Liebel-Flarsheim Co. v. Medrad, Inc., supra, 358 F.3d at 904-05 (internal quotation marks omitted); see Phillips v. AWH Corp., supra, 415 F.3d at 1323; SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1352 (Fed. Cir. 2005), petition for cert. filed, 74 U.S.L.W. 3260 (U.S. Oct. 13, 2005) (No. 05-489); Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1368-69 (Fed. Cir. 2004).

The Court must also look to the specification because the patentee may have acted "as his own lexicographer" by giving a special definition to a claim term that differs from the term's plain and ordinary meaning. Phillips v. AWH Corp., supra, 415 F.3d at 1316. If the patentee defines a term, his definition

governs the term's construction. Phillips v. AWH Corp., supra, 415 F.3d at 1316. To redefine a claim term, a patentee "must clearly express that intent in the written description." Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1370 (Fed. Cir.), cert. denied, 126 S.Ct. 488 (2005); see Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1177 (Fed. Cir. 2002) ("[The] heavy presumption in favor of the claim term's ordinary meaning is overcome, however, if a different meaning is clearly and deliberately set forth in the intrinsic evidence." (internal quotation marks omitted)); Renishaw PLC v. Marposs Soecieta' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998) ("The patentee's lexicography must, of course, appear with reasonable clarity, deliberateness, and precision before it can affect the claim." (internal quotation marks omitted)); Vitronics Corp. v. Conceptronic, Inc., supra, 90 F.3d at 1582 ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."). As the Federal Circuit has explained, however, "an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment." E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369 (Fed. Cir. 2003).

If it is in evidence, the Court may also consider the patent's prosecution history. However, because the prosecution history represents an ongoing negotiation with the Patent and

Trademark Office, it "often lacks the clarity of the specification and thus is less useful for claim construction purposes." Phillips v. AWH Corp., supra, 415 F.3d at 1317.

The Court may in its discretion also consider extrinsic evidence, such as expert and inventor testimony, dictionaries and treatises to assist in educating it in the field of the invention. Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004); Markman v. Westview Instruments, Inc., supra, 52 F.3d at 979; see Phillips v. AWH Corp., supra, 415 F.3d at 1314, 1318. Although extrinsic evidence may be useful to the Court, "it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Phillips v. AWH Corp., supra, 415 F.3d at 1319.

B. Disputed Terms

The parties disagree as to the meaning of three terms: (1) "a therapeutically effective amount" in Claim 1 of the '569 Patent and Claim 1 of the '565 Patent; (2) "benzalkonium chloride" in Claim 1 of the '565 Patent; and (3) "about" in Claims 2 and 3 of the '569 Patent and Claims 1, 17 and 18 of the '565 Patent (Pl. Memo. at 1). Because the terms' definitions can be derived from intrinsic evidence, namely the claims themselves,

the specifications and, where submitted, the prosecution history, I do not consider any proffered extrinsic evidence.[1]

[1]Plaintiffs assert that extrinsic evidence should be used in this case and, citing Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002), rely in part on a dictionary and an expert for their proposed constructions (Plaintiffs' Responsive Claim Construction Brief ("Pl. Resp."), Docket Item 58, at 3). However, the parties filed their briefs prior to the recent decision Phillips v. AWH Corp., supra, 415 F.3d at 1320, in which the Federal Circuit stated:

> [T]he methodology [adopted by Texas Digital] placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias and too little on intrinsic sources, in particular the specification and prosecution history. While the court noted that the specification must be consulted in every case, it suggested a methodology for claim interpretation in which the specification should be consulted only after a determination is made, whether based on a dictionary, treatise, or other source, as to the ordinary meaning or meanings of the claim term in dispute. . . . In effect, the Texas Digital approach limits the role of the specification in claim construction to serving as a check on the dictionary meaning of a claim term if the specification requires the court to conclude that fewer than all the dictionary definitions apply, or if the specification contains a sufficiently specific alternative definition or disavowal. That approach, in our view, improperly restricts the role of the specification in claim construction.

(Internal citations omitted). Because I find that the disputed claims can be construed using only intrinsic evidence and in light of Phillips, I do not rely on extrinsic evidence for the construction.

1. "A Therapeutically Effective Amount"

The first disputed claim term, "a therapeutically effective amount," appears in Claim 1 of both the '569 and '565 Patents. Plaintiffs assert that "a therapeutically effective amount" should be construed to mean "an amount of calcitonin sufficient to produce a desired therapeutic effect" (Pl. Memo. at 9). They claim that this is the term's plain meaning and that this interpretation is supported by the specifications (Pl. Memo. at 9). Defendants contend that the term should be construed to mean "an amount of calcitonin when administered as a nasal spray or drop prepared as per the teachings of the '565 and '569 patent[s] [sufficient] to produce the desired therapeutic activity. The amount of calcitonin depends upon the source of calcitonin, the condition to be treated, desired frequency and the desired effect" (Def. Memo. at 12). Defendants claim that their definition should be adopted because it is taken directly from the '569 and '565 Patents' specifications (Def. Memo. at 12; see '569 Patent at col. 5, lines 44-49 ("The amount of calcitonin to be administered in accordance with the method of the invention and hence the amount of active ingredient in the composition of the invention will, of course, depend on the particular calcitonin chosen, the condition to be treated, the desired frequency

of administration and the effect desired."); '565 Patent at col. 5, lines 43-48 (same)).

I first consider the plain and ordinary meaning of the claim as it would be read by one of ordinary skill in the art and conclude that "a therapeutically effective amount" of calcitonin is the amount of calcitonin that will produce the desired curative, or therapeutic, change, or effect. Thus, the plain meaning suggests that the term should be construed, as plaintiffs have proposed, as "an amount of calcitonin sufficient to produce a desired therapeutic effect." This construction is not contradicted by other claim language.

Although defendants contend "a therapeutically effective amount" should be qualified by the conditions set forth in the second sentence of their proposed construction, their construction is not supported by logic and appears to run afoul of the prohibition against importing limitations set forth in the specifications into the claims themselves.

First, defendants' suggested construction -- "an amount of calcitonin when administered as a nasal spray or drop prepared as per the teachings of the '565 and '569 patent[s] [sufficient] to produce the desired therapeutic activity. The amount of calcitonin depends upon the source of calcitonin, the condition to be treated, desired frequency and the desired effect" -- is internally inconsistent. Its first sentence defines "therapeuti-

cally effective amount" as the amount that produces the "desired therapeutic activity." Its second sentence, however, suggests that "desired effect," is only one of the factors that, in defendants' view, defines "therapeutically effective amount." Thus, defendants' definition is inconsistent with respect to whether the desired effect or activity is the factor that determines a therapeutically effective amount or merely one of the factors that determines a therapeutically effective amount.

Although there can be no serious question that the specification must be consulted in construing a patents claims, the Court of Appeals for the Federal Circuit has repeatedly warned that limitations set forth in the specifications should not be imported into the claims. Varco, L.P. v. Pason Sys. USA Corp., 436 F.3d 1368, 1373 (Fed. Cir. 2006); CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1231 (Fed. Cir. 2005); Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1326 (Fed. Cir. 2002). Although "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be difficult to apply in practice," Phillips v. AWH Corp., supra, 415 F.3d at 1323, the Federal Circuit has offered the following counsel:

> To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. See Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524,

> 1533 (Fed. Cir. 1987). One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. See SciMed Life Sys., 242 F.3d at 1341. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent. See Snow v. Lake Shore & M.S. Ry. Co., 121 U.S. 617, 630, 7 S.Ct. 1343, 30 L.Ed. 1004 (1887) (it was clear from the specification that there was "nothing in the context to indicate that the patentee contemplated any alternative" embodiment to the one presented).

Phillips v. AWH Corp., supra, 415 F.3d at 1323; accord Lizardtech, Inc v. Earth Resource Mapping, Inc., 433 F.3d 1373, 1377 (Fed. Cir. 2006) (Lourie, J., concurring); Lasermax, Inc. v. Glatter, 01 Civ. 6500 (LMM), 2005 WL 1981571 at *3 (S.D.N.Y. Aug. 17, 2005)

Reading the specification in light of the foregoing admonition, I conclude that the factors set forth in the specification relevant to the quantification of a "therapeutically effective amount" were included as part of the specification's teaching function and are not limits on the claimed invention. The second sentence of defendants' proposed construction appears in the specification of each patent between a discussion of the ethers that can be used in the compositions claimed by the patents ('569 Patent, col. 4 line 29 - col. 5, line 43; '565 Patent, col. 4 line 31 - col. 5, line 42) and the range of

calcitonin dosages that can be administered by the compositions and methods claimed by the patents ('569 Patent, col. 5, line 61 - col. 6, line 19; '565 Patent, col. 5 line 60 - col. 6, line 18). The particular classes of ethers discussed in the specifications are expressly incorporated into the claims ('569 Patent, Claims 18-19; '565 Patent, Claims 11-14), just as the particular dosage ranges discussed in the specifications are also expressly incorporated into the claims ('569 Patent, Claims 11-14; '565 Patent, Claims 5-8). The presence of the specific ethers and dosage ranges in the specifications and claims of both patents strongly suggests that the omission from the claims of the factors relevant to quantifying a "therapeutically effective amount" was intentional and that these factors were included in the specifications to teach one skilled in the art to practice the invention, but not to define or limit the claimed invention. If the patentee intended the factors listed in the specifications to be read into the claims, it is inconceivable that it would be omitted from the claim language in light of the other limitations that were expressly imported to the claims from the specifications.

Thus, I conclude that the term "a therapeutically effective amount" should be construed as "an amount sufficient to produce a desired therapeutic effect."

2. "Benzalkonium Chloride"

The parties next dispute whether a functional limitation should be incorporated into the term "benzalkonium chloride" as it is used in Claim 1 of the '565 Patent. The parties are in agreement as to most of the term's proper construction. Plaintiffs claim the term means "pharmaceutically acceptable mixtures of quaternary ammonium salts of the generalized formula C_6H_5-CH_2-$NR(CH_3)_2Cl$, wherein R is C_8H_{17} to $C_{18}H_{37}$" (Pl. Memo. at 11). Defendants claim the term means "a concentration of benzalkonium chloride that increases the bioavailability of calcitonin when administered to the nasal mucosa. Benzalkonium chloride is the name commonly employed for known mixtures of quaternary ammonium salts typically of the generalized formula C_6H_5-CH_2-$NR(CH_3)_2Cl$, wherein R is C_8H_{17} to $C_{18}H_{37}$" (Def. Memo. at 13). Thus, the distinction in the proposed constructions lies in defendants' addition of the functional limitation on the definition of benzalkonium chloride to "concentration[s] of benzalkonium chloride that increase the bioavailability of calcitonin when administered to the nasal mucosa."

Considering the language of the claim itself first, I find the additional limitation proposed by defendants contradicts the language of the claim itself and should, therefore, be rejected. Claim 1 of the '565 Patent expressly defines the amount of benzalkonium chloride as a range from "about 0.002% to

about 0.02% on a weight per volume basis of a benzalkonium chloride." Adding the functional limitation proposed by defendants, here "increasing the bio-availability of calcitonin," contradicts the unqualified plain language in the claim. See Phillips v. AWH Corp., supra, 415 F.3d at 1324 (claim construction process cannot be used to contradict unambiguous claim language); Crystal Semiconductor Corp. v. Tritech Microelec. Int'l, Inc., 246 F.3d 1336, 1349 (Fed. Cir. 2001) (rejecting claim construction that would contradict express claim language); Scientific Games Int'l, Inc. v. Oberthur Gaming Technologies, 1:02 CV 3224 TWT, 2005 WL 3307522 at *6 (N.D. Ga. Dec. 5, 2005) (same).

Plaintiff also correctly argues that one skilled in the art would not read the name of a chemical compound as implying any particular amount of that compound (Pl. Memo. at 13). The plain and ordinary meaning of a chemical compound is simply that compound, without any limitation as to amount. For example, the sodium chloride, or table salt, in a postage-stamp sized package at a cafeteria's condiment bar is just as much sodium chloride as a truckload of the same material. The name of a composition simply does not imply an amount. Thus, one skilled in the art would read benzalkonium chloride to mean "pharmaceutically acceptable mixtures of quaternary ammonium salts of the generalized formula C_6H_5-CH_2-$NR(CH_3)_2Cl$, wherein R is C_8H_{17} to $C_{18}H_{37}$."

This construction is not contradicted by other claim language or the specification.

Defendants argue that the specification and prosecution history support their construction of the term because, they contend, that plaintiffs distinguished their claims "over prior art references on the basis that the inventive calcitonin formulation included an amount of benzalkonium chloride which provides an unexpected improvement by increasing the bioavailabilty of calictonin upon nasal administration" (Def. Memo. at 13-15).

The portion of the specification on which defendants rely states:

> In accordance with the present invention it has now been surprisingly found that pharmaceutical compositions can be obtained comprising a calcitonin as active ingredient which meet the high standards of stability and tolerability required for nasal application and which are, for example, eminently suitable for use in multiple dose spray applicators, i.e. applicators capable of delivering a series of individual dosages over e.g. [sic] period of several days or weeks, by the use of benzalkonium chloride as a co-ingredient and preserving agent. Surprisingly it has also been found that use of benzalkonium chloride, even at the very low concentration required for use as a preserving agent, may confer beneficial advantages in relation to the nasal resorption characteristics of calcitonin containing compositions and hence enhance calcitonin bio-availability levels consequential to nasal application.

('565 Patent, col. 2, lines 52-67). Defendants contend that this language makes it clear that the "concentration of benzalkonium chloride must be sufficient in concentration so as to confer the beneficial advantage of enhanced bioavailability levels for

calcitonin upon nasal application" (Def. Memo. at 14). Plaintiffs again argue that using this language in the construction improperly reads a limitation from the specification into the claim (Pl. Memo. at 13-14).

I agree with plaintiffs that accepting defendants' proposed construction would improperly read a limitation from the specification into the claim. As noted above, Claim 1 of the '565 Patent expressly claims a fairly specific range of concentrations of benzalkonium chloride to be added to the composition and does not qualify that range by stating any functional limitation. Where a claimed composition expressly sets forth the amount of an ingredient, either by precise amount or by range of amounts, it is improper to import a functional limitation from the specification to vary the scope of the claim.[2]

An analogous issue was presented in Jeneric/Pentron, Inc. v. Dillon Co., 205 F.3d 1377, 1382-83 (Fed. Cir. 2000). In that case, the patentee of a composition used in dental restorations sought to enjoin defendant's manufacture and sale of an allegedly infringing composition. The relevant claim language limited the amount of cerium oxide in the composition to 0 - 1%.

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[2]Indeed, defendants themselves admit as much, stating, "functional limitations expressed in the specification but not in the claim may not be read into the claim terms" (Def. Mem. at 9). See also Micro Chem., Inc. v. Great Plains Chem. Co., Inc., 194 F.3d 1250, 1258 (Fed. Cir. 1999); Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1278 (Fed. Cir. 1995).

Although the accused product, marketed under the name "Sensation," contained 1.61% cerium oxide, plaintiff claimed that it literally infringed because the cerium oxide in defendant's composition performed the same function as the cerium oxide in the claimed composition. The Federal Circuit rejected plaintiff's literal infringement argument, stating:

> Claim 1 requires a two-phase dental porcelain composition with 0-1% of cerium oxide. Claim 1 does not place functional limitations on the percentage of cerium oxide, thus distinguishing opacifying, coloring, or fluorescing cerium oxide from anti-greening cerium oxide. Rather, the claim specifies 0-1% cerium oxide. Sensation contains 1.61% - an amount well outside the precisely claimed range. This court rejects any attempt to carve out a portion of cerium oxide according to functions not recited in the claim. Jeneric's infringement theory essentially proposes that the precisely claimed ranges do not limit the amount of porcelain compositions. That argument fails because it would read out of claim 1 the express claim ranges. See Unique Concepts, 939 F.2d at 1563. Thus, this court agrees with the district court's determination that Jeneric has not shown a reasonable likelihood of success on literal infringement by Sensation.

205 F.3d at 1382-83.

Claim 1 of the '565 Patent also sets forth a range of the concentration of benzalkonium chloride in the claimed composition. As in Jeneric/Pentron, importing the functional limitation suggested by defendants would read that quantitative limitation out of the patent. Thus, Jeneric/Pentron requires that defendants' argument be rejected.

Defendants further argue that in the prosecution of the '565 Patent, plaintiffs expressly relied on the "unexpected

benefit" of benzalkonium chloride quoted in the specification quoted above to distinguish plaintiffs' invention from prior art. Thus, defendants contend, the language should be read into Claim 1 because it would be improper for plaintiffs to rely on this feature to distinguish prior art in their patent application and then deny its significance in later litigation (Def. Memo. at 15-21).

Defendants are correct that the prosecution history distinguishes the invention from prior art, at least in part, by emphasizing that adding benzalkonium chloride to the composition can increase absorption and bioavailability (e.g., Def. Memo. Ex. F at 3). However, enhanced absorption and bioavailability were not the only features cited to distinguish prior art. Plaintiffs also cited improved "tolerability and ciliary function"[3] (Def. Mem. Ex. F at NX 2280 & Ex. G at NX 2292). Moreover, Claim 1 of the '565 Patent claims compositions with beneficial amounts of benzalkonium chloride by limiting the claimed compositions to those that contain from "about 0.002% to about 0.02% on a weight per volume basis of [] benzalkonium chloride" -- the precise range of amounts found to provide the greatest benefit (see '565 Patent at col. 3, lines 47-50 ("A preferred concentration for the

[3]"The nasal mucosa is lined with small hairs called 'cilia' covered with mucous. The cilia transports mucous and foreign particles to the throat. This function is essential to human health" (Klibanov Decl. at 9, n.2).

benzalkonium chloride component in the compositions of the invention is from about 0.002 to about 0.02, typically about 0.01% (w/v) of the total composition.")). Since the patentee chose to claim a numerically-defined range of benzalkonium chloride concentrations that confers the "surprising" benefit, there is no reason to convert that quantitative limitation into a qualitative one.

Finally, adoption of defendant's proposed functional limitation would lead to inconsistent definitions of benzalkonium chloride in the '569 and '565 Patents. Since the '569 and '565 Patents result from the same application, identical terms in both patents should be construed to have the same meaning. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003); Fin. Control Sys. Pty, Ltd. v. OAM, Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001). Claim 1 of the '569 Patent claims a composition that includes "an effective amount of benzalkonium chloride to enhance the bioavailability of said calcitonin when administered, to the nasal mucosa . . . ." If the functional limitation suggested by defendants were read into the definition of benzalkonium chloride, the functional limitation that is expressly set forth in Claim 1 of the '569 Patent would be redundant and meaningless. See Merck & Co. v. Teva Pharms. USA, Inc., supra, 395 F.3d at 1372 ("A claim construction that gives

meaning to all the terms of the claim is preferred over one that does not do so.").

Therefore, I find that "benzalkonium chloride," as the term is used in the '565 patent, should be construed as "pharmaceutically acceptable mixtures of quaternary ammonium salts of the generalized formula C_6H_5-CH_2-$NR(CH_3)_2Cl$, wherein R is C_8H_{17} to $C_{18}H_{37}$."

3. "About"

The final claim term in issue is "about" as it is used in Claims 2 and 3 of the '569 patent and Claims 1, 17 and 18 of the '565 patent.[4] Plaintiffs contend that "about" should mean "approximately" (Pl. Memo. at 14); defendants contend it should mean "limited to the precise lower and upper limits of the recited range" (Def. Memo. at 22-23).[5]

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[4]The relevant language in the '569 Patent is in Claim 2: "[a] composition according to claim 1 having a pH of from about 3 to about 5" (emphasis added); and Claim 3: "[a] composition according to claim 2, having a pH of from about 3.5 to 4.5" (emphasis added). The relevant language in the '565 Patent is in Claim 1: "about 0.002% to about 0.02% on a weight per volume basis of a benzalkonium chloride" (emphasis added); Claim 17: "[a] composition according to claim 1 having a pH of from about 3 to about 5" (emphasis added); and Claim 18: "[a] composition according to claim 17 having a pH from about 3.5 to 4.5" (emphasis added).

[5]Plaintiffs argue there is no need to construct this term because defendants have already admitted their composition is within the ranges plaintiffs' patents claim under either proposed constructions for all claims in which construction of the term

(continued...)

The plain and ordinary meaning of "about," and how it would be read by one skilled in the art, is "approximately." Defendants point to no language in the specifications or prosecution history that suggests the inventors redefined "about" in a manner contrary to its plain and ordinary meaning.

Construing "about" to mean "approximately" is consistent with another claim in the patent in suit that states a range but has no qualifying term preceding it (see '565 Patent Claim 14 ("A composition according to claim 13 comprising a polyoxyethylene cholesteryl ether in which the number of repeating units in the polyoxyethylene moiety is from 16 to 26."). This range is limited to the precise upper and lower numbers cited. If "about" were construed as limiting ranges to their precise upper and lower limits, the use of "about" would be superfluous when contrasted with a range that has no preceding qualifying language. Because, as noted above, "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so," I find defendants' proposed construction must be rejected because it would render the term "about" meaningless. Merck & Co. v. Teva Pharm. USA, Inc., supra, 395 F.3d at 1372

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[5](...continued)
"about" is disputed (Pl. Resp. at 7-8). Despite these admissions, in the interest of completeness, at this stage of the suit I find it is more prudent to construct each of the disputed claim terms.

Defendants argue that if "about" is construed to mean "approximately," it will be impossible to determine the precise bounds of the claims' ranges for purposes of invalidity and infringement (Def. Memo. at 23). This reasoning is flawed. A patent is not invalid merely because claims approximate certain values within it. See Merck & Co. v. Teva Pharm. USA, Inc., supra, 395 F.3d at 1369-72 (constructing term "about" that preceded numeric value to mean "approximately"); Jeneric/Pentron, Inc. v. Dillon Co., supra, 205 F.3d 1377, 1381 (Fed. Cir. 2000) (ranges in claim preceded by "about" were approximations and claims not preceded by "about" or a similar qualification were precise figures). The inventors are permitted to patent approximate measurements for their composition and, thus, construing the term "about" to mean "approximately" is also permissible.

For these reasons, I find that the term "about" should be construed to mean "approximately."

IV. Conclusion

For the reasons stated above, I find that: (1) the term "a therapeutically effective amount" as it is used in Claim 1 of the '569 Patent and Claim 1 of the '565 Patent should be construed to mean "an amount sufficient to produce a desired therapeutic effect"; (2) the term "benzalkonium chloride" as it is used in Claim 1 of the '565 Patent should be construed to mean

"pharmaceutically acceptable mixtures of quaternary ammonium salts of the generalized formula C_6H_5-CH_2-$NR(CH_3)_2Cl$, wherein R is C_8H_{17} to $C_{18}H_{37}$"; and (3) the term "about" as it is used in Claims 2 and 3 of the '569 Patent and Claims 1, 17 and 18 of the '565 Patent should be construed to mean "approximately."

Dated: New York, New York
March 13, 2006

SO ORDERED

HENRY PITMAN
United States Magistrate Judge

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